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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/293,533	04/15/99	CHATTERJEE	M 304142000201

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EXAMINER	
HELMS,L	
ART UNIT	**PAPER NUMBER**
1642	10

DATE MAILED: 11/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/293,533	Chatterjee et al
Examiner	**Group Art Unit**
Larry R. Helms Ph.D.	1642

☒ Responsive to communication(s) filed on *2 Oct 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *62-89* is/are pending in the applicat

Of the above, claim(s) *64-67 and 78-81* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *62, 63, 68-77, and 82-89* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election without traverse of species A, melanoma, in Paper No. 8 is acknowledged. The claims reading on the elected species are claims 62, 63, 68-77 and 82-89.

2. Claims 64-67, 78-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 8.

3. Claims 62, 63, 68-77, and 82-89 are under examination and will be examined to the extent the GD2-associated tumor is melanoma.

Drawings

4. The response filed 4/15/99 has been carefully considered but is deemed to be partially persuasive. The response states that the declaration of S. Chatterjee was deemed sufficient in the parent case in which the drawings were amended. In response to this argument, the declaration of S. Chatterjee is persuasive to explain the changes to the Figures, however, the proposed drawing correction filed on 4/15/99 has been disapproved because it is not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).

Specification

5. The disclosure is objected to because of the following informalities:

a. The amendment filed 4/15/99 to the specification on page 12, lines 12-23 has been entered, however, the amendment to the specification does not need brackets or underlining (see MPEP 714.22 (a)(1)(iii).

b. The amendment filed 4/15 to page 85 line 4 to page 86 line 5 contains numbers that are bolded. It is unclear why the numbers are bolded.

c. The first line of the specification needs to be updated to list the current status of all U.S. applications.

d. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Information Disclosure Statement

6. The U.S. Patents contained in the Information Disclosure Statement filed 4/15/99 has been considered, however, All other documents listed on the PTO-1449 has not been considered because the parent application 08/591196 was not available. The IDS has been placed in the file and if Applicants would supply the Examiner with the copies of the references listed as 23-102 the Examiner will then conceder the references.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 75 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 75 and 89 are indefinite for reciting "said antibody is heat-treated prior to administration" because the exact meaning of the phrase is not clear. It is not clear what temperature is intended or what is "heat-treating an antibody".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 62, 63, 68-75 and 89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of delaying the development of a GD2-associated tumor in an individual wherein the tumor is a melanoma, wherein said method comprises administering an antibody comprising a light and heavy chain variable region

sequence of SEQ ID NO:2 and 4, respectively, in an adjuvant of aluminum hydroxide, wherein the amount of the antibody is about 2mg and is administered at weekly or bi-weekly intervals and wherein the antibody is added with aluminum hydroxide and incubated to about 45°C for 30 minutes prior to administration, does not reasonably provide enablement for a method of delaying the recurrence of melanoma in an individual comprising administering an antibody wherein the light and heavy chain variable region sequences are SEQ ID NO2 and 4, respectively, in an adjuvant of aluminum hydroxide, wherein the amount of the antibody is about 2mg and is administered at weekly or bi-weekly intervals and wherein the antibody is heat-treated prior to administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a method of delaying the recurrence of a melanoma in an individual comprising administering an antibody comprising a light and heavy chain sequence of SEQ ID NO:2 and 4 and wherein the antibody is heat-treated prior to administration.

The specification teaches a method for treating mice, rabbits, and humans with melanoma with the 1A7 antibody with an adjuvant QS-21(see pages 73-80 and see pages 91-98). The specification teaches administration of the 1A7 antibody with aluminum hydroxide and incubating to about 48°C prior to administration (see page 54, lines 15-16). The specification fails to enable a method of delaying the recurrence of melanoma in an individual. The specification also fails to teach heating the 1A7 antibody to any temperature other than 48°C for 30 minutes prior to administration.

The scope of the claims is not commensurate with the enablement provided in the specification. The specification does not disclose whether the method is effective in an individual which also encompasses humans with pre-existing melanoma and the individual does not have any manifestations of the disease, and this is a significant omission in view of the well-known immunosuppressive effects of certain tumors. There is no evidence provided to indicate that 1A7 would lessen the recurrence of melanoma in an individual. The criticality of a working example encompassing all of the method steps, especially the treatment of pre-existing melanoma, is underscored by Gura et al (Science Vol 278 11/97 1041-1042) in a discussion of potential shortcomings of extrapolating from in vitro studies and animal studies to similar procedures in cancer patients. Gura et al teaches that "xenograft tumors don't behave like naturally occurring tumors in humans" (page 1041, second col, second full paragraph) and that there were "gross difference in sensitivity in real tumors in mice and in the clonogenic assay" (page 1042, second col, second full paragraph). Further, Gura teaches that clonogenic assays

"cannot tell researchers how anticancer drugs will act in the body" (page 1042, first-second col, bridging paragraph). One skilled in the art would reasonably conclude that evidence obtained in mouse or rabbit models would not correlate with results expected in humans patients.

In addition, the specification fails to enable an antibody that is "heat-treated" to any unspecified temperature and time and obtains the claimed properties of delaying recurrence or delaying development of a melanoma in an individual. One skilled in the art would not expect an antibody that was heated to any undetermined temperature such as 100°C or more for an unspecified time to function and bind antigen or produce the claimed properties as broadly encompassed by claims 75 and 89.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Priority

11. Applicants claim for U.S. Priority to 08/372,676, now U.S. Patent 5,612,030 is acknowledged, however, the limitations of SEQ ID Nos 2 and 4 are not seen in this application. Therefore, claims 62-89 are granted the priority date of application 08/591,196, now U.S. Patent 5,977,316, filed 1/16/96, for which SEQ ID Nos 2 and 4 are disclosed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 76-77, and 82-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (U.S. Patent 5,612,030, filed 1/17/95) and further in view of Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988).

a. The claims recite a method for delaying development of a melanoma in an individual comprising administering an antibody comprising a light and heavy chain of SEQ ID NO:2 and 4 in an adjuvant of aluminum hydroxide in an amount of about 1 or 2 mg at weekly or biweekly intervals and the antibody is heat-treated prior to administration.

b. Chatterjee et al teach the 1A7 antibody and a method of treating melanoma with the antibody administered at 2mg using an adjuvant QS-21(see column 6-7 and column 11, lines 13-22) and the antibody generates an immunity to GD2 which is expressed on malignant melanoma cells (column 4, lines 60-64). Chatterjee et al also teach administering at bi-weekly intervals of the antibody in Freund's adjuvant (column 6, lines 30-34) and the "effective dosage for mammals may vary due to such factors as age, weight, activity level or condition of the subject being treated." (Column 11, lines 13-15) . Chatterjee et al does not teach that the adjuvant is aluminum hydroxide. This deficiency is made up for in the teachings of Harlow et al.

c. Harlow et al teach adjuvants of aluminum hydroxide.

d. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the 1A7 antibody of Chatterjee et al and an adjuvant of aluminum hydroxide as taught by Harlow et al.

e. One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Chatterjee et al teach administering the antibody in an adjuvant for treatment of patients with melanoma (column 7, lines 13-16). In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Harlow et al teach "A common alternative to the use of Freund's adjuvant is to absorb the immunogen onto an aluminum salt[]. Aluminum hydroxide is the most commonly used, but all types avoid many of the more harmful side effects of Freund's adjuvants.". Thus, it would have been obvious to one of skill in the art at the time of the claimed invention was made to have used aluminum hydroxide as an adjuvant with the 1A7 antibody for treatment of melanoma in an individual.

f. Although claim 76 recites the antibody comprises the light and heavy chain variable region sequences of SEQ ID NO:2 and 4, it is the Examiner's position that Chatterjee et al have produced an anti-idiotypic antibody named 1A7 that is named the same as the antibody in the instant application and Chatterjee's antibody was raised against the anti-GD2 mAb 14G2a as the antibody in the instant application. One of ordinary skill in the art would reasonably conclude that Chatterjee et al's antibody also possesses the same binding, functional and structural characteristics and the same amino acid sequence for the light and heavy chain as the antibody in the instant application, therefore, it appears that Chatterjee et al have produced an antibody that is

identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Chatterjee et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

g. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

15. Claims 76-77, 82-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (J. Immunol. 150 (8 part 2) 142A Abstract 805, 1993) and further in view of Saleh et al (the Journal of Immunology 151:3390-3398, 1993) and Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988).

a. The claims have been described supra.

b. Chatterjee et al teach the anti-idiotypic antibody 1A7 which is an antibody against the GD2 on melanoma cells. Chatterjee et al does not teach specifically a method for delaying the development of melanoma in an individual comprising administering the antibody with aluminum hydroxide. These deficiencies are made up for by the teachings of Saleh et al and Harlow et al.

c. Saleh et al teach a method comprising administering an anti-idiotypic antibody that mimics the GD2 antigen with Freund's adjuvant to an individual at two week intervals (see page 3392).

d. Harlow et la has been described supra.

e. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the 1A7 antibody of Chatterjee et al in the method of Saleh and an adjuvant of aluminum hydroxide as taught by Harlow et al.

f. One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method of Saleh et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Chatterjee et al teach "This mAB2 will be characterized further in GD2 positive animal tumor models for tumor protection experiments..it could be then used for active immunotherapy of patients with melanoma and other GD2 positive tumors.". In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method of Saleh et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Harlow et al teach "A common alternative to the use of Freund's adjuvant is to absorb the immunogen onto an aluminum salt[]. Aluminum hydroxide is the most commonly used, but all types avoid many of the more harmful side effects of Freund's adjuvants.". In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method

of Saleh et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Saleh et al teach "These studies demonstrate that the human anti-id 4B5 mimics the GD2 antigen and is capable of eliciting both a hemoral and cellular anti-GD2 immune response. This antibody could be potentially used as a human anti-id vaccine in patients with malignant melanoma." (See abstract). Thus, it would have been obvious to one of skill in the art at the time of the claimed invention was made to have used aluminum hydroxide as an adjuvant with the 1A7 antibody for treatment of melanoma in an individual as taught by Seleh et al. Although claims 84-89 recite amounts of the antibody and intervals of administration, it would have been obvious to optimize amounts and conditions of administration. "It is not inventive to point out a particular range of conditions or optimum working ranges if what is involved is nothing more than the skill of the mechanic and the exercise of 'patient experimentation'." Duplan Corp. v. Deering Milliken, Inc., 444 F. Supp. 648, 197 USPQ 342 (D.S.C. 1977) aff'd 594 F.2d 979,201 USPQ 641 (4th Cir. 1979).

g. Although claim 76 recites the antibody comprises the light and heavy chain variable region sequences of SEQ ID NO:2 and 4, it is the Examiner's position that Chatterjee et al have produced an anti-idiotypic antibody named 1A7 that is named the same as the antibody in the instant application and Chatterjee's antibody was raised against the anti-GD2 mAb 14G2a as the antibody in the instant application. One of ordinary skill in the art would reasonably conclude that Chatterjee et al's antibody also possesses the same binding, functional and structural characteristics and the same amino acid sequence for the light and heavy chain as the antibody in

the instant application, therefore, it appears that Chatterjee et al have produced an antibody that is identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Chatterjee et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

h. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

16. Claims 76-77 and 82-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (J. Immunol. 150 (8 part 2) 142A Abstract 805, 1993) and further in view of Cheung et al (Int. J. Cancer 54:499-505, 1993) and Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988).

a. The claims have been described supra.

b. Chatterjee et al teach the anti-idiotypic antibody 1A7 which is an antibody against the GD2 on melanoma cells. Chatterjee et al does not teach specifically a method for delaying the development of melanoma in an individual comprising administering the antibody with aluminum hydroxide. These deficiencies are made up for by the teachings of Cheung et al and Harlow et al.

c. Saleh et al teach a method comprising administering an anti-idiotypic antibody that mimics the GD2 antigen with Freund's adjuvant (see abstract and page 502).

d. Harlow et la has been described supra.

e. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the 1A7 antibody of Chatterjee et al in the method of Cheung et al and an adjuvant of aluminum hydroxide as taught by Harlow et al.

f. One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method of Cheung et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Chatterjee et al teach "This mAB2 will be characterized further in GD2 positive animal tumor models for tumor protection experiments..it could be then used for active immunotherapy of patients with melanoma and other GD2 positive tumors.". In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method of Cheung et al with the adjuvant of aluminum hydroxide as taught by Harlow et al because Harlow et al teach "A common alternative to the use of Freund's adjuvant is to absorb the immunogen onto an aluminum salt[]. Aluminum hydroxide is the most commonly used, but all types avoid many of the more harmful side effects of Freund's adjuvants.". In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the 1A7 antibody of Chatterjee et al in the method of Cheung et al with the adjuvant of aluminum hydroxide as taught by Harlow et al

because Cheung et al teach the antibodies that we characterized are instrumental for induction of Ab3 and protective immunity in animal models and potentially in patients carrying GD2-positive tumors. (See page 504) and Cheung et al demonstrate Ab3 induced by mice immunized with Ab2s. Thus, it would have been obvious to one of skill in the art at the time of the claimed invention was made to have used aluminum hydroxide as an adjuvant with the 1A7 antibody for treatment of melanoma in an individual as taught by Cheung et al. Although claims 84-89 recite amounts of the antibody and intervals of administration, it would have been obvious to optimize amounts and conditions of administration. "It is not inventive to point out a particular range of conditions or optimum working ranges if what is involved is nothing more than the skill of the mechanic and the exercise of 'patient experimentation'." Duplan Corp. v. Deering Milliken, Inc., 444 F. Supp. 648, 197 USPQ 342 (D.S.C. 1977) aff'd 594 F.2d 979,201 USPQ 641 (4th Cir. 1979).

g. Although claim 76 recites the antibody comprises the light and heavy chain variable region sequences of SEQ ID NO:2 and 4, it is the Examiner's position that Chatterjee et al have produced an anti-idiotypic antibody named 1A7 that is named the same as the antibody in the instant application and Chatterjee's antibody was raised against the anti-GD2 mAb 14G2a as the antibody in the instant application. One of ordinary skill in the art would reasonably conclude that Chatterjee et al's antibody also possesses the same binding, functional and structural characteristics and the same amino acid sequence for the light and heavy chain as the antibody in the instant application, therefore, it appears that Chatterjee et al have produced an antibody that is

identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Chatterjee et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

h. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusions

17. No Claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

SHEELA HUFF
PRIMARY EXAMINER

Larry R. Helms Ph.D.

703-306-5879